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K060795

DEC 18 2006

November 27, 2006

510(k) K060795 Non-Confidential Summary of Safety and Effectiveness

Official Contact:	John Dennis, Strategic Counsel Sàrl
Proprietary or Trade Name:	Somnofit
Common Name:	Anti-snoring device
Descriptive Name:	Mandibular Advancement Device (MAD)
Device Classification Name:	Device, Anti-snoring
Product Code:	LRK – Anti-Snoring Device
Classification Reference:	21 CFR 872.5570
Device Class:	Class II
Intended Use:	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA).

Substantial Equivalence

Substantial equivalence is made with predicate anti-snoring devices, which are fitted over the lower and upper teeth by "boil and bite" or "boil and fit". Once fitted over the lower and upper jaws, these devices advance the lower jaw forward by connecting with a slight pressure the two jaws at an angle thereby pulling the lower jaw slightly forward. These devices are also referred to as "mandibular advancement devices" with the same intended use of reducing snoring and sleep apnea.

The Somnofit device is of a similar design and functions in a similar manner to other comparable predicate devices and the intended uses are the same. The general differences or modifications between this device and predicate devices are minor and do not raise new safety concerns. Specific predicate devices that fall in this category include:
The Respironics Silencer (K033822)
SUAD Device (K023836)
SleepBite (K013808)
TAP (K962516)
NorAD (K013049)

Device Description and intended use

Like these predicate devices, Somnofit is intended as an aid in the alleviation of snoring by positioning the lower jaw slightly forward thereby freeing the air intake and releasing back the tongue thereby decreasing air obstruction and turbulence. The device is normally placed in users' mouth each evening prior to sleeping and removed from the mouth the following morning. The device fits one user, is multi-use and cleaned daily.

The Somnofit anti-snoring device consists of:

- Lower plate fitted over lower teeth

- Upper plate fitted over upper teeth
- Hook mechanism, two located on right and left side of upper plate, four hooks on lower plate, two on left side and two on right side used to connect two bands one on the right upper and right lower plates, the other on the left upper and left lower plates.
- A floating thermometer
- A ventilated storage box
- A packet of 100 orthodontic rubber bands
- Instructions

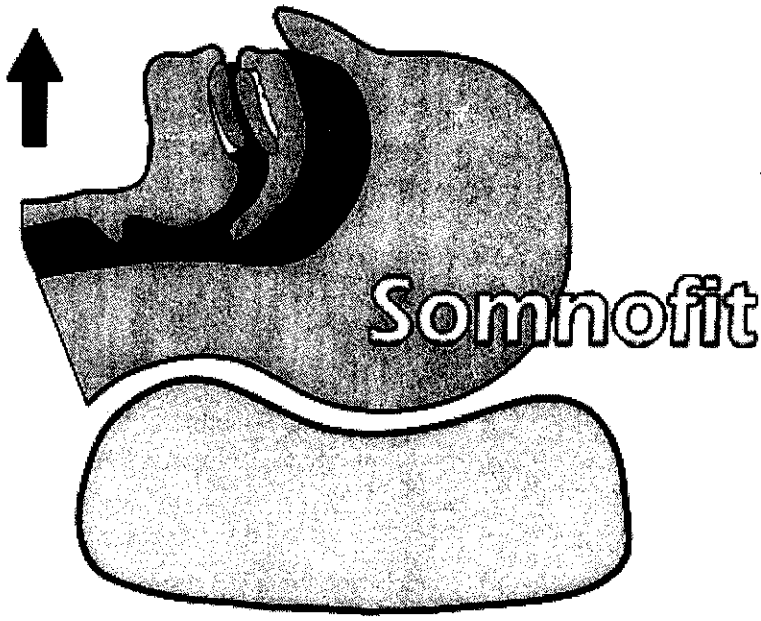
The two buccal mouldings (upper and lower) are designed for universal application in adults with the use of one-size-fits all. The dentist or physician takes a dental impression, by immersing each moulding in hot water, as indicated with the included thermometer in order to soften the impressible plastic material then pressing the plates against the user's upper and lower jaws in order to form a fitting to the size dimensions of user's jaws and teeth. Once individually fit the first time, there is no need to reheat/re-mold the two plates. The upper and lower jaws fittings are linked by way of two orthodontic elastic bands connected by way of hooks located on the right and left front part of the plates. Two sets of hooks are present on both sides of the lower plate to allow the user to choose a looser or tighter tension of the bands. The upper single hook is located in front of the lower two sets of hooks. This way the bands thrust the lower jaw forward a few millimeters in front of the upper jaw. The elastic bands permit full lateral and vertical movement of device as well as some horizontal movement in user's mouth.

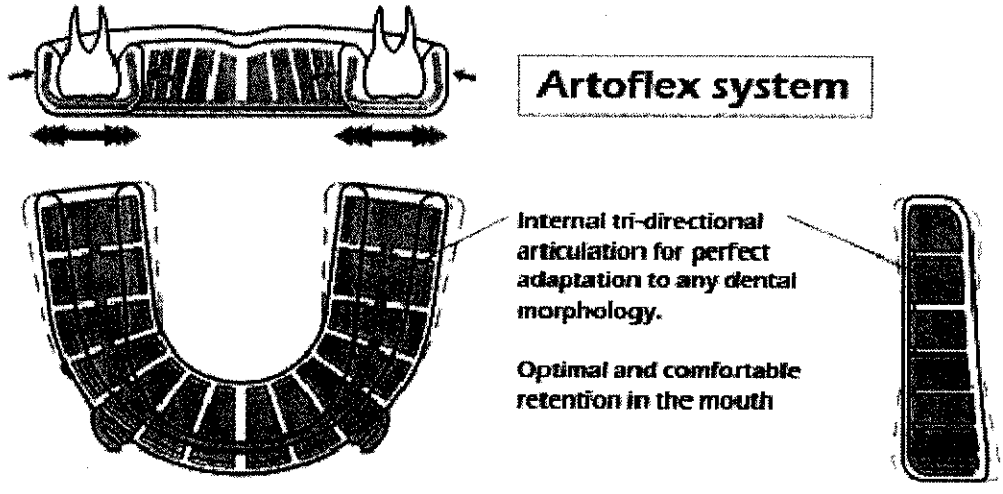
Table 1: Risk Profile

Identified risk	**Special controls**
Intraoral gingival, palatal or dental soreness	
Obstruction of oral breathing	The angle of the elastic bands connecting the upper and lower plates ensures a positioning of the lower jaw a few millimeters in front of upper jaw thereby expanding passageway, decreasing air obstruction.
Loosening or flaring of lower anterior teeth or General tooth movement	The frames are designed to cover most of the teeth thereby dispersing the pressure from the elastic bands over a wider group of teeth.

Encompassed inside the outer layer is a "skeleton" band, which is rigid in material but is made of a chain of rectangles with gaps in between. The gaps allow the whole band to optimally fit to the width of each tooth. This provides for a better fit over most of the user's teeth. With the molding pre-fitted to the user's dental morphology, the elastic traction is distributed over the 18- to 24- teeth.

Diagrams and Materials Used





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2006

OSCIMED SA
C/O Mr. John Dennis
Strategic Counsel Sarl
42754 Edwards Ferry Road
Leesburg, Virginia 20176

Re: K060795
Trade/Device Name: Somnofit
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring Intraoral and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: December 4, 2006
Received: December 11, 2006

Dear Mr. Dennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

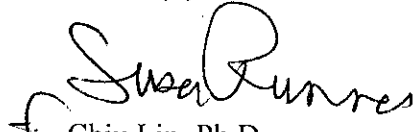
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): **K060795**

Device Name: **Somnofit**

Indications For Use: **To reduce or alleviate snoring and mild to moderate obstructive sleep apnea.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K060795